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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,914	10/13/2005	Gary A. Clawson	14017-009US1	6907
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EXAMINER				
MCGARRY, SEAN				
ART UNIT		PAPER NUMBER		
1635				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/552,914

Applicant(s)

CLAWSON ET AL.

Examiner

Sean R. McGarry

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 143-162 is/are pending in the application.
- 4a) Of the above claim(s) 143-159 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 160-162 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

In response to applicant amendments filed 10/13/08, the following new rejection is made. This rejection supersedes the rejection of record. Any rejection made in the previous Official Action and not repeated herein is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 160-162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsen et al [US 6,013,447] in view of Taira et al [US 2004/0002077] and Hertz et al [Journal of Lipid Research, Vol. 41: 1082-1086, 2000].

The invention is as clearly set forth in the claims.

Nilsen et al have taught a vectors and methods of their use in identifying effector RNA molecules (see Figure 1, for example). The vectors are taught to contain a "targeting gene" which encodes an effector RNA which is "an RNA molecule that is designed to alter, or preferably inhibit, the expression of an RNA of interest" where "preferred effector RNA molecules are ribozymes, external guide sequences, antisense RNA, and triple helix-forming RNA" (see columns 8-9, for example). These effector molecules are targeted to a fusion transcript that encodes a target nucleic acid molecule fused to a reporter molecule that can be directly or indirectly detected including a fluorescent polypeptide fusion (see columns 6-7, for example). Nilsen et al have taught a vector construct as recited for use in the instantly claimed method where the vector of Nilsen is used to identify effector RNA molecules. Nilsen et al does not explicitly direct one to use weak promoters, but indicates at column 8, lines 5-10, that any suitable promoter can be used. At column 8, lines 39-49, various preferred promoters are suggested and includes the HSV thymidine kinase promoter which is known in the art as a weak promoter. The difference between the prior art and the instant invention is the recitation of an RNA effector that induces RNA interference. RNA interference was not known at the time of Nilsen's invention, but would be RNA effectors since they are RNA oligomers that inhibit a target nucleic acid such as an mRNA. The prior art does indeed

provide a description of such effectors expressed from a vector as required by the instant claims.

Taira et al have taught the expression of double stranded siRNA molecules from a vector where there is clearly a "promoter region" that provides for the expression of short double stranded RNAs (see Figures 1 and 2, for example).

Hertzel et al have taught the use of weak promoters in the expression of genes in adipose cells. It is taught that weak promoters are useful in the study of low-expressing genes. The study was performed using fluorescent reporters (see especially page 1085, for example).

Clearly one in the art would include the siRNA compounds of Taira et al in the vectors taught by Nilsen et al. Nilsen et al clearly describe their vectors for the general purpose of identifying RNA effector molecules of which siRNA would clearly be a member. Nilsen et al have taught that the vectors provide for an efficient method of detecting effective RNA effector molecules through the use of reporter target RNA fusions. One intent on detecting effective effector molecules to inhibit low-expressing genes would look to the use of weak promoters as shown by Hertzel et al. The limitation of claim 162 where the polypeptide is lethal is considered an obvious variation for the following reasons. First, it is noted that the claim does not limit the polypeptide lethality to be due to the reporter aspect or the target RNA aspect of the fusion. Since the vector of Nilsen et al also comprises a second reporter it would have been a fine tool to detect the inhibition of lethal nucleic acids in a cell since the second reporter would provide evidence that the surviving cells contained the vector with the test effector RNA

targeting a lethal target gene, for example. Furthermore, Nilsen et al teach that a reporter molecule can be directly or indirectly detectable. Clearly a reporter that is lethal would provide for a detection of cells inhibiting the fusion polypeptide and those that do not.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 10/13/08 have been fully considered but they are not persuasive. Applicant argues the prior art differs from the amended invention since the prior art does not teach the use of weak promoters. First applicant mischaracterizes the teachings of Nilsen et al at column 8, lines 13-16 and lines 39-49. Applicant asserts that Nilsen prefers strong promoters such as as. . . Nilsen et al do not use the term "strong promoter" anywhere that applicant has cited. There are strong promoters listed as well as weak promoters such as the HSV tk promoter. Applicant argument appears to be based on the argument that preferred embodiments somehow teach away from the claimed invention is addressed by the MPEP At 2123 [R-5] Rejection Over Prior Art's Broad Disclosure Instead of preferred Embodiments

I. PATENTS ARE RELEVANT AS PRIOR ART FOR ALL THEY CONTAIN

"The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part

of the literature of the art, relevant for all they contain.” In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also > Upsher-Smith Labs. v. Pamlab, LLC, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005)(reference disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component);< Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. “The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.”).

Nevertheless Hertz et al have taught specifically the use of weak promoters for the same reason applicant asserts for their use in the instant specification at page 43-44.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean R McGarry
Primary Examiner
Art Unit 1635

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